

**Claims:**

1. A **drug delivery device or system** comprising:
  - a) a **medical device adapted for local application or administration in hollow tubes**; and, in conjunction therewith,
  - b) a **therapeutic dosage of an anti-inflammatory ascomycin derivative** in free form or, where such forms exist, in pharmaceutically acceptable salt form.
2. A device or system according to claim 1 wherein the anti-inflammatory ascomycin derivative is **pimecrolimus** in free form or, where such forms exist, in pharmaceutically acceptable salt form.
3. A device or system according to claim 1 or 2 wherein the medical device is a catheter-based delivery device or an intraluminal device adapted for local application or administration in hollow tubes.
4. A device or system according to claim 1 or 2 wherein the medical device is a catheter-based delivery device, a local injection device or system, an intraluminal or indwelling device adapted for local application or administration in hollow tubes, a stent, a coated stent, an endolumenal sleeve, a stent-graft, a controlled release matrix, a polymeric or biological endoluminal paving, or an adventitial wrap.
5. A device or system according to claim 1 or 2 wherein the anti-inflammatory ascomycin derivative is affixed to the medical device in a way allowing drug release.
6. A device or system according to claim 1 or 2 which comprises a coated stent.
7. **Use of an anti-inflammatory ascomycin derivative in free form or, where such forms exist, in pharmaceutically acceptable salt form, in the preparation of a medicament for the prevention and treatment of inflammatory complications following vascular injury, such as:**

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- prevention or treatment of **vascular inflammation or smooth muscle cell proliferation and migration, or aneurysm expansion in hollow tubes, or increased extracellular matrix degradation and erosion in hollow tubes, or increased inflammatory cell infiltration, or increased cell proliferation or decreased apoptosis, or increased matrix deposition or degradation, or increased positive, aneurysmal remodeling (aneurism dilation) following device placement; or**
- treatment of **intimal thickening or aneurysm expansion in vessel walls; or**
- stabilising **atherosclerotic plaques, or stabilising sites of aneurysm; or**
- stabilising or reducing **aneurysm dilation at the site of aneurysm.**

8. **A method of treatment of inflammatory complications following vascular injury, such as for:**

- preventing or treating **vascular inflammation or smooth muscle cell proliferation and migration, or aneurysm expansion in hollow tubes, or increased extracellular matrix degradation and erosion in hollow tubes, or increased inflammatory cell infiltration, or increased cell proliferation or decreased apoptosis, or increased matrix deposition or degradation, or increased positive, aneurysmal remodeling (aneurism dilation) following device placement in a mammal in need thereof, comprising administration of a therapeutically effective amount of an anti-inflammatory ascomycin derivative;**
- treating **intimal thickening or aneurysm expansion in vessel walls in a mammal in need thereof, comprising controlled delivery from a catheter-based or intraluminal medical device of a therapeutically effective amount of an anti-inflammatory ascomycin derivative;**
- stabilising **atherosclerotic plaques or stabilising sites of aneurysm, or stabilising or reducing aneurysm dilation at the site of aneurysm in a mammal in need thereof, comprising administration of a therapeutically effective amount of an anti-inflammatory ascomycin derivative;**

**optionally together with one or more other active ingredients;**  
**whereby the anti-inflammatory ascomycin derivative is in free form or, where such forms exist, in pharmaceutically acceptable salt form.**

9. A method according to claim 8 wherein the underlying condition beneficially affected is stenosis, restenosis, vascular inflammation, thrombosis, unstable angina, myocardial infarction, heart failure, ischaemia, sudden death, stroke and/or aneurysm rupture, and wherein the anti-inflammatory ascomycin derivative is administered from a stent or from a coating applied to a stent or is administered in conjunction with a stent.